

**Thomsen J, Sass K, et al. Local Overpressure Treatment Reduces Vestibular Symptoms in Patients with Ménière's Disease: A Clinical, Randomized, Multicenter, Double-Blind, Placebo-Controlled Study. *Otology and Neurotology* 2005;26:68-73.**

Design: Randomized clinical trial

Population/sample size/setting:

- 40 patients (age and sex not reported precisely, median age in the 40s) treated for established Ménière's disease at 8 university hospitals in Sweden, Denmark, and Norway
- Eligibility based on age 20 to 65, diagnosis of definite Ménière's according to American Academy of Otolaryngology (AAO) criteria, with hearing loss of 20 to 65 dB in the frequencies 500 Hz, 1 kHz, 2 kHz, and 3 kHz, with at least 8 attacks of vertigo lasting at least 20 minutes in the preceding year
- Exclusion criteria were any previous inner ear surgery, any systemic disease treated with steroids, any use of diuretics or vasodilators within 2 weeks of entry into study, active bilateral disease, or any previous destructive procedure (e.g., gentamicin injection); purely vestibular symptoms, pregnancy, and any suspicion of perilymphatic fistula

Main outcome measures:

- All patients had placement of ventilation tubes followed by 2 months of monitoring for vertigo
- Only patients who had at least 2 attacks of vertigo during the monitoring period were eligible to continue with the study and to be randomized
- Randomization was to either an active intervention with a localized overpressure device (n=20) or to an identical-appearing placebo device (n=20)
- Duration of placebo-controlled treatment was 8 weeks
- Primary outcomes were based on diary entries during the final 4 weeks of treatment: change in frequency of vertigo, change in the AAO functionality profile, and change in patient perception of vertigo on a visual analog scale
- Group comparisons were based upon permutation tests using matched pairs of observations, although the matching of patients into pairs is not clearly stated
- Of the three primary outcomes, the change in frequency of vertigo was not significantly associated with treatment, but the AAO functionality and the vertigo VAS scores were favorably associated with the active treatment device
- Several secondary outcomes (tinnitus, hearing, patient perception of aural pressure) were not significantly associated with treatment group

Authors' conclusions:

- Local overpressure treatment is a noninvasive, nondestructive, and safe way to reduce hydrops in Ménière's disease

Comments:

- The reason for the method of analysis is not explained, but appears to use paired observations with little explanation about the variables on which the pairs were matched
- Because the analysis of vertigo intensity takes VAS data (which should be on a continuous scale) and transforms it into a form in which each matched pair has a score of +1, -1. or 0, it is possible that some analytical power was lost; this is difficult to determine
- The three primary outcomes appear to have been of equal importance in the analytical scheme
- The analysis of the AAO functionality scores appears to have been done on ranks rather than in matched pairs; the ranks were “stratified” but the stratifying variables are not specified—the method of randomization is not clear
- The treatment effect in Table 1 compares the number of attacks in the “after” period of 4 weeks and the number in the “before” period of 8 weeks; the actual frequency reduction may be much less dramatic than it appears to be
- Graphic displays of data in Figures 1 and 2 are an uninformative substitute for a tabular display of data; there also needs to be a tabular display of baseline data for the two treatment groups

Assessment: Inadequate for evidence regarding the positive pressure intervention device (randomization method unspecified, lack of description of demographics of population, lack of baseline comparisons in a clear form)